UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois Corporation,	)	
Plaintiff/Counterclaim-Defendant,	)	
v.	)	**Civ. No. 07-CV-00754-GMS**
BANNER PHARMACAPS, INC., a Delaware Corporation,	)	
Defendant/Counterclaim-Plaintiff.	)	

BANNER'S RESPONSE TO ABBOTT'S SUPPLEMENTARY AUTHORITY

Abbott Laboratories ("Abbott") erroneously asserts that *Celgene Corp. v. KV Pharmaceutical Co.*, Slip. Op., 2008 WL 2856469 (D.N.J. July 22, 2008) "completely undermines" Banner's Unfair Competition counterclaim. *Celgene* is distinguishable because it arose in a different context. Further, Abbott misconstrues the case.

1. *Celgene*, a district court case not binding on this Court, is entirely distinguishable because it involved sanctions under Fed. R. Civ. P. Rule 11, and not the ability to maintain an unfair competition counterclaim which is the issue here.

2. *Celgene* is also not in point here, because the underlying infringement facts are entirely different. Banner's unfair competition counterclaim rests on the fact that Banner sought approval for a drug that could not reasonably have been viewed as infringing Abbott's patents. Banner detailed its proposed drug in its detailed statement of non-infringement sent to Abbott. Banner sought approval only for valproic acid, while all the claims of both Abbott patents expressly required a 1:1 molar ratio of *sodium*

valproate and valproic acid. Where patent claims require two specific ingredients, and a proposed drug has only one of the ingredients, no one can reasonably argue that the drug is within the patent claims. In contrast, *Celgene* did not discuss any non-infringement facts at all, which suggests that there was no similar non-infringement issue presented.

3. Abbott also misconstrues the case, by reading the decision to ignore the plain wording of the relevant statutes. First, Abbott reads *Celgene* in a way that is inconsistent with §505(j)(2)(B)(iv)(II) of the Food, Drug, and Cosmetic Act – which was enacted at the same time, and as part of the same scheme, as 35 U.S.C. §271(e). That FDA section requires that an applicant making a Paragraph IV certification provide the patentee with "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. §355(j)(2)(B)(iv)(II). The detailed statement requirement exists only to permit an infringement determination.

If Congress had allowed that a patentee to sue upon the mere filing of a Paragraph IV certification, without regard to actual infringement, there would have been no need for the statute to require the applicant to provide the detailed statement. The statute would have permitted a patentee to sue upon mere notice of a Paragraph IV certification. Therefore, Abbott's interpretation of *Celgene* requires a conclusion that the statutory detailed statement requirement is superfluous, contravening the well-established principle of statutory construction that each provision of a statute must be given effect. *See e.g., New Castle County v. Halliburton NUS Corp.*, 111 F.3d 1116, 1123 (3rd Cir. 1997) ("[A] statute should be construed so that effect is given to all its provisions, so that no part will

be inoperative or superfluous, void or insignificant") (quoting *Pennsylvania Med. Soc'y v. Snider*, 29 F.3d 886, 895 (3d Cir.1994)).[1]

4. Abbott's interpretation is also erroneous, because it ignores the plain wording of 35 U.S.C. §271(e)(2). That statute limits infringements only to drugs that fall within the scope of the patent claims:

> (e) (2) It shall be an act of infringement to submit—
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug ***claimed in a patent or the use of which is claimed in a patent***. . . . .

Abbott reads-out the critical phrase of the statute – "claimed in a patent or the use of which is claimed in a patent." If Abbott's interpretation of *Celgene* and the statute was correct, §271(e)(2) would have said only "It shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug," and leave off the rest of the statutory language. That additional language has meaning. A patentee may properly charge infringement of §271(e)(2) only if the patentee has reasonable basis to believe that the drug in the Paragraph IV certification was "a drug claimed in a patent." The well-pleaded rule requires the Court to assume that Abbott had no such basis when it sued.

5. The *Celgene* court did err in suggesting that §271(e)(2) always absolves a patentee from Rule 11 obligations if a certification is filed. That suggestion not only violates the plain language of §271(e)(2) and the FDA statute as discussed above, but also misapprehends the statutory scheme. The filing of an ANDA Paragraph IV

[1] It would also violate the ordinary presumption that the legislature did not intend an unreasonable, absurd or unworkable result when enacting a statute. *Johnson v. Physicians Anesthesia Service, P.A.*, 621 F.Supp. 908 (D.C. Del. 1985). *See also In re Kaiser Aluminum Corp*., 456 F.3d 328 (3rd Cir. 2006), citing *Griffin v. Oceanic Contractors, Inc*., 458 U.S. 564, 575 (1982); *United States v. Schneider*, 14 F.3d 876, 880 (3d Cir.1994).

certification is merely an "artificial" act of infringement, and it does not mean that a drug is within the scope of any patent claim. The Supreme Court explained: "Quite obviously, the purpose of subsection (e)(2) [35 U.S.C. §271(e)(2)] is to enable the jurisdictional adjudication upon which the ANDA scheme depends." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).[2] The Paragraph IV certification defines a future drug, and not one that otherwise had been made, used, imported or sold under the traditional infringement provision, 35 U.S.C. §271(a). Therefore, a separate provision had to be created to provide a jurisdictional basis for suit. However, just like §271(a) still requires that a product be within the scope of a patent claim to be infringing, §271(e)(2) also requires a determination that the certification encompasses "a drug claimed in a patent."

Thus, filing a Paragraph IV certification does not, by itself, establish that a patent is infringed. Rather, after filing, the case proceeds like any other patent case, and the patentee does not prevail unless it proves that the patent would actually be infringed. Because the artificial act of infringement described in §271(e)(2) is jurisdictional only, the submission of a Paragraph IV certification does not alone justify litigation. The patentee must have a reasonable basis, based on the applicant's detailed statement, that the proposed certified drug infringes.

For the foregoing reasons, Abbott's citation of supplemental authority does not support its position, and Abbott's Motion to Dismiss should be denied.

Respectfully Submitted,

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[2] *See also Celgene Corp. v. Teva Pharms, USA, Inc.*, 412 F.Supp.2d 439, 445 (D.N.J. 2006): "[Section 271(e)(2)] exists for the very limited purpose of creating a technical infringement so that [the] courts can decide whether or not a proposed generic drug, if manufactured, would infringe. Its purpose is to permit the matter to be decided before . . . an actual, rather than artificial, act of infringement occurs."

Dated: August 14, 2008 By: __/s/ *Anna Martina Tyreus*____

George Pazuniak (DE # 478)
Anna Martina Tyreus (DE # 4771)
WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
222 Delaware Avenue, Suite 1501
Wilmington, Delaware 19801
Telephone: (302) 252- 4320
Email: GPazuniak@wcsr.com
Email: MTyreus@wcsr.com

Attorneys for Banner Pharmacaps Inc.

Of Counsel:

Charles J. Raubicheck
Naomi J.L. Halpern
FROMMER LAWRENCE & HAUG, LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

CERTIFICATE OF SERVICE

I, AnnaMartina Tyreus, hereby certify that on August 14, 2008, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, and copies were caused to be served upon the following counsel of record via electronic mail:

Paul E. Crawford, Esquire
Connolly, Bove, Lodge & Hutz
The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899
(302) 658-9141
pcrawford@cblh.com
Attorney for Plaintiff

/s/ *AnnaMartina Tyreus*
AnnaMartina Tyreus